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<p>(21) International Application Number: PCT/SE99/00803 (22) International Filing Date: 12 May 1999 (12.05.99) (30) Priority Data: 9801685-0 14 May 1998 (14.05.98) SE (71) Applicant (for all designated States except US): ATOS MEDICAL AB [SE/SE]; P.O. Box 183, S-242 22 Hörby (SE). (72) Inventor; and (75) Inventor/Applicant (for US only): PERSSON, Jan-Ove [SE/SE]; Björkgatan 45, S-243 34 Höör (SE). (74) Agent: STRÖM &amp; GULLIKSSON AB; P.O. Box 4188, S-203 13 Malmö (SE).</p>		<p>(81) Designated States: AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GD, GE, GH, GM, HR, HU, ID, IL, IN, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, SL, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ZW, ARIPO patent (GH, GM, KE, LS, MW, SD, SL, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, CY, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, GW, ML, MR, NE, SN, TD, TG).</p> <p><b>Published</b> With international search report. Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments. In English translation (filed in Swedish).</p>
<p>(54) Title: VOCAL VALVE WITH FILTER</p> <p>(57) Abstract</p> <p>A vocal valve for connection to a tracheostoma comprises a filter (16) for moisture and heat exchange at breathing through the vocal valve, and a housing (15) receiving the filter and having a first opening at one side of the filter to be connected to the tracheostoma, and at least one second opening at the opposite side of the filter, which communicates with the surroundings. A manually operated valve element (15') for blocking the air passage through the filter is constructed to close said first opening at manual operation thereof.</p> <p>11 13 15' 13A 15 17 16 14 12 10</p>		

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### Vocal Valve with Filter

The invention relates to a vocal valve to be applied  
5 to a tracheostoma.

A tracheostoma is opened in case a patient has difficulties to breath in a natural way, e.g. due to formation of phlegm, or in case the patient has been laryngeectomized involving excision of the larynx and the vocal cords no  
10 connection existing between trachea and the mouth. In the latter case a voice prosthesis often is placed by surgery in a fistula in the wall between trachea and esophagus in order that the patient notwithstanding the lack of vocal cords shall be able to produce speech, which is done by  
15 pressing air through the voice prosthesis to esophagus where speech is produced by the mucous membranes being put into vibration. In order that this can take place it is necessary to close the tracheostoma when speech is to be produced, and this is done either by the patient covering  
20 the tracheostoma with the fingers or by closing manually a valve located in the tracheostoma. It is necessary to close the tracheostoma also in case the vocal cords are still there because the air otherwise will escape through the tracheostoma instead of escaping via the vocal cords and  
25 the mouth in the usual way, but in the latter case the valve can comprise a check valve which opens at inspiration and closes at expiration because the expiration can take place in the normal manner via the vocal cords and the mouth.

30 For laryngeectomized patients automatic vocal valves have been proposed (US-A-4 582 058 and US-A-4 325 366) which are kept opened during normal breathing but close by a pressure shock being produced in trachea when the patient wishes to produce speech. Valves of this type do not function sufficiently well on patients with a tracheal cannula  
35

and therefore are taped directly against the skin of the patient's neck.

On laryngeectomized patients who inspire and expire through the tracheostoma, a regenerative moisture and heat exchanger, a so-called "artificial nose", is connected with the tracheostoma. It is formed as a filter which absorbs moisture and heat from the expiration air said moisture and heat then being given off to the inspiration air (SE-B-348 643 and SE-B-467 195). It has also been proposed according to WO-A-95/17138 to combine such a filter with a valve which can be operated manually in order to close the tracheostoma.

Tracheotomized patients often have some type of cannula, i.e. a curved tube which is passed through the tracheostoma into trachea and the purpose of which is to keep the tracheostoma open and to form a holder for a vocal valve and/or a moisture and heat exchanger which, however, instead can be taped directly against the skin on the patient's neck.

The vocal valve according to the invention is of the kind disclosed in WO-A-95/17138 and comprises a filter for moisture and heat exchange at breathing through the vocal valve, a housing receiving the filter and having a first opening at one side of the filter to be connected to the tracheostoma, at least one second opening at the opposite side of the filter, communicating with the surroundings, and a manually operated valve element for blocking the air passage through the filter.

In the vocal valve according to WO-A-95/17138 the airflow through the tracheostoma via the filter is blocked by closing said second opening at manual operation of the valve element. This involves a clear drawback because only a limited area can be provided in a plane of the opening and thus of the filter in order to effect a sealed closing; otherwise the vocal valve at the necessary filter volume

will be unreasonably high. A small area of the filter implies bad moisture and heat exchange.

The purpose of the invention is to overcome this drawback which is achieved by the vocal valve according to the invention having the characterizing features of claim 1  
5 whereby great freedom is achieved with regard to the construction of the filter which can be dimensioned for optimal moisture and heat exchange function, the valve element at the same time having to close a small area only, which  
10 requires a very small force at operation of the valve element. If on the contrary the valve element shall close an optimal filter area in the vocal valve according to WO-A-95/17138 a considerably greater force is required, which causes inconvenience for the patient particularly if the  
15 vocal valve is provided with a cannula because this passes into a very delicate area of the patient. Above all patients which have recently undergone surgery are very susceptible.

In order to explain the invention in greater detail a  
20 number of embodiments will be described below reference being made to the accompanying drawings in which

FIG 1 is a side view, partly in axial cross-section, of a first embodiment of the vocal valve according to the invention,

25 FIG 2 is an end view of the filter for the regenerative moisture and heat exchanger,

FIG 3 is a plan view of the housing receiving the filter,

30 FIG 4 is a cross-sectional view of the housing receiving the filter, and illustrates the manual operation for blocking the air passage through the filter,

FIG 5 is a view corresponding to FIG 1 with a suction catheter passed through the vocal valve,

FIG 6 is a view similar to FIG 1 of a second embodiment of the vocal valve according to the invention, FIG 7 is a side view of the housing receiving the filter,

5 FIG 8 is a cross-sectional view of the filter and the housing receiving the filter, FIG 9 is a plan view of the housing, FIG 10 is a view similar to FIG 4, which illustrates the manual operation for blocking the air passage

10 through the filter, FIG 11 is a view similar to FIG 6 of a modification of the vocal valve in FIGS. 6-9, FIG 12 is a view similar to FIG 1 of a third embodiment of the vocal valve according to the invention,

15 FIG 13 is a view similar to FIGS. 4 and 10 of the embodiment in FIG 12, FIG 14 is a view similar to FIG 5 of the embodiment in FIG 12, FIG 15 is an axial cross-sectional view of a fourth

20 embodiment of the invention, FIG 16 is a plan view of the embodiment in FIG 15, and FIG 17 is a view similar to FIG 4 and illustrates manual operation of the vocal valve according to

25 FIGS. 15 and 16.

Referring to FIGS. 1-3 the embodiment of the vocal valve according to the invention shown therein comprises a curved tracheal cannula 10 to be inserted into a tracheostoma and provided with two flexible wings or flaps 11 which

30 are fixed against the skin of the neck by means of a strap passed around the neck and attached to the flaps. The flaps 11 are attached to the lower side of a flange 12 on the tracheal cannula, and a bushing 14 consisting of an ISO-cone for connection to a respirator or another apparatus is

35 provided between the flange 12 and an end flange 13 pro-

vided on the tracheal cannula, which forms the seat surface 13a of the vocal valve. A housing 15 is mounted on the bushing 14 and comprises a socket of relatively soft plastics open at both ends. In cross-section the housing has

5 substantially rectangular shape with rounded corners as can be seen from FIG 2. Inside the housing two filter bodies 16 are provided which are retained therein between an end grid 17 and the part of the tracheal cannula 10 which projects into the housing. The filter bodies can consist of a foam

10 material e.g. foamed polyurethane impregnated with calcium chloride.

At breathing through the vocal valve the expiration air passes through the tracheal cannula 10 and enters the housing 15 through the opening surrounded by the seat 13A

15 in order then to pass through the filter bodies 16 to the surrounding air, while the inspiration air passes in the opposite direction into the tracheal cannula 10. The filter bodies form a regenerative moisture and heat exchanger, heat and moisture being absorbed by the filter from the

20 expiration air in order then to be given off to the inspiration air.

When speech is to be produced the passage of air through the vocal valve shall be blocked in order that the expiration air shall be expelled through the mouth via the

25 vocal cords or - for a laryngeectomized patient - via a voice prosthesis in the wall between trachea and esophagus, and this is effected according to FIG 4 by deforming the housing 15 with a finger and sealingly engage the housing with the seat surface 13A. In order to facilitate the

30 deformation of the valve housing 15 a portion 15' thereof, centered over the seat surface 13A, is made with a smaller wall thickness than the rest of the valve housing. In this portion of the valve housing weakening lines 18 are provided as an impervious cross, and by pressing a blunt

35 object e.g. a pencil against the centre of this cross the

wall of the filter housing can be penetrated, four pointed flaps being established so that an opening is provided in the housing wall through which a suction catheter 19, FIG 5, can be introduced into trachea through the tracheal can-  
5 nula 10 for sucking away phlegm from trachea in patients having a large phlegm production and difficulties to cough off such phlegm. When the material of the valve housing 15 is relatively soft the flaps will retain their original position after withdrawal of the suction catheter so that  
10 the opening in the housing wall will again be substantially closed. Since only a minor number of patients need phlegm suction this embodiment is advantageous. The alternative would be that the vocal valve has to be supplied in two versions one with a suction port and one without, because  
15 patients which need no phlegm suction do not want to have an open suction port in the vocal valve.

In the embodiment of the vocal valve according to the invention which is disclosed in FIGS. 6-9 the valve housing is made of two parts 15A and 15B the part 15A forming a  
20 bottom plate which at an upwardly projecting collar 20 is passed onto the ISO-cone 14. The part 15B forms a cover on the bottom plate 15A and is connected with the bottom plate in order to enclose the filter bodies 16. The cover 15B has a number of openings 21 in order to communicate the inte-  
25 rior of the valve housing with the surrounding air via the filter bodies 16.

In order to block the air passage through the vocal valve the cover 15B can be deformed with a finger in order to sealingly engage the cover with the valve seat 13A as  
30 shown in FIG 10 and described above. In this case the bottom plate 15A is provided with a nipple 22 for connection of an oxygen hose. This nipple can consist of a fixedly arranged nipple or, alternatively, can consist of a separate nipple which is inserted into a connection aperture in  
35 the valve housing.



In the same manner as described above a suction catheter can be passed through an aperture in the valve housing said aperture being opened by penetrating an impervious cross 18 on the cover 15B in the same manner as disclosed in FIG 5.

A modification of the embodiment in FIGS. 6-9 is disclosed in FIG 11 the tracheal cannula 10 being omitted in this modification and the flaps 11 being attached directly to the lower side of the bottom plate 15A. In this embodiment the collar 20 is extended upwards to form the seat surface 13A. The passage formed by the collar 20 communicates directly with the tracheostoma when the vocal valve is attached to the patient by the flaps 11 being taped against the skin of the patient's neck.

Instead of being made of a soft material the valve housing 15 can be made of a rigid material and a separate valve element can be provided inside the valve housing for co-operation with the valve seat 13A, said valve element being operated from the outside of the valve housing. For example, the valve element can have a valve stem projecting through an aperture in the valve housing in the portion 15'. Such an embodiment is disclosed in FIGS 12 and 13. A valve disc 23 is connected to the cover 15B at the inside thereof and has a socket 24 projecting through an aperture 25 in the cover. Normally the valve disc 23 and the socket 24 are in this position which is shown in FIG 12 but can be operated manually from the outside by means of a finger to engage sealingly the valve disc under elastic deformation with the seat surface 13A as shown in FIG 13. A cross of impervious weakening lines can be provided in the bottom wall 26 of the socket 24 in the manner described above in order to allow a suction catheter to be passed through the valve housing into and through the tracheal cannula as disclosed in FIG 14.

In the embodiment according to FIGS. 16 and 17 the valve housing comprises a bottom part 15A and a cover part 15B, the bottom part 15A being attached to a flexible flange 11A and the cover part 15B being connected with the bottom part 15A. Inside the cover part 15B a filter body 16 is provided, and this part is made with a number of apertures 27 around an impervious central portion 28 in order to communicate the interior of the valve housing with the surroundings via the filter body 16 which covers the apertures 27. A plate 29 inside the cover part 15B has a central ring 30 through which the interior of the valve housing communicates with the tracheostoma when the vocal valve is attached to the patient by the flange 11A being taped against the skin of the patient's neck with the ring 30 centred on the tracheostoma. When the patient with a finger presses on the impervious central portion 28 of the cover part 15B said part will be deformed and also the filter body 16 which will be sealingly engaged with and compressed against the seat surface 13A formed by the ring 30, as shown in FIG 17, in order to block the air passage through the vocal valve.

In this embodiment the cover part 15B with the filter body 16A can comprise a replaceable filter unit, the bottom part 15A being intended to be used permanently for application of the replaceable filter unit over the tracheostoma.

In all the embodiments of the vocal valve according to the invention, which have been described, the opening communicating with the tracheostoma is closed in order to block the air flow through the vocal valve the regenerating moisture and heat exchanging filter as a consequence thereof can be dimensioned for optimal function without the vocal valve projecting unacceptably far from the tracheostoma. In case the vocal valve is combined with a tracheal cannula the optimally dimensioned filter can be located inwardly of the cannula end (the seat surface 13A).

The vocal valve according to the invention involves a low manufacturing cost, particularly in case the wall of the valve housing is deformed in order to close the vocal valve and to block the air flow therethrough, because the  
5 vocal valve in this embodiment has no moving parts.

## CLAIMS

1. Vocal valve for connection to a tracheostoma, comprising a regenerating filter (16) for moisture and heat exchange at breathing through the vocal valve, a housing  
5 (15) receiving the filter and having a first opening at one side of the filter to be connected to the tracheostoma, at least one second opening at the opposite side of the filter, communicating with the surroundings, and a manually operated valve element (15', 23) for blocking the air pas-  
10 sage through the filter, **characterized** in that the valve element is constructed to close said first opening at manual operation thereof.

2. Vocal valve according to claim 1, **characterized** in that said first opening comprises the end opening of a tra-  
15 cheal cannula (10).

3. Vocal valve according to claim 1, **characterized** in that said first opening is bounded by a sealing surface (13A) formed by the housing (15).

4. Vocal valve according to claim 3, **characterized** in  
20 that the sealing surface (13A) is formed by the end surface of a socket (20; 30) projecting into the interior of the housing.

5. Vocal valve according to any of claims 1-4, **characterized** in that the manually operated valve element com-  
25 prises a wall portion (15') of the housing (15), which can be deformed resiliently in order to be sealingly engaged with said first opening.

6. Vocal valve according to any of claims 1-4, **characterized** in that the manually operated valve element com-  
30 prises a wall portion (28) of the housing (15), which can be resiliently deformed in order to press the filter (16) located between the wall portion and said first opening, under compression thereof against said first opening and into sealing engagement therewith.

7. Vocal valve according to claim 5 or 6, **characterized** in that the housing (15) consists of a relatively soft material.

8. Vocal valve according to any of claims 5-7, **characterized** in that the resiliently deformable wall portion (15') of the housing (15) has reduced wall thickness.

9. Vocal valve according to claim 1, **characterized** in that the housing (15) comprises a socket open at both ends with said first opening located between two filter bodies (16) located one at each end of the socket.

10. Vocal valve according to any of claims 1-3, **characterized** in that the manually operated valve element comprises a valve disc (23) in the housing (15), having an operating member (24) available at the outside of the housing.

11. Vocal valve according to claim 10, **characterized** in that the valve disc comprises a resiliently deformable plate (23) connected to the housing.

12. Vocal valve according to any of claims 1-11, **characterized** in that the housing (15) is provided with a cross of impervious weakening lines (18) for penetration of the housing under opening of a suction catheter port.

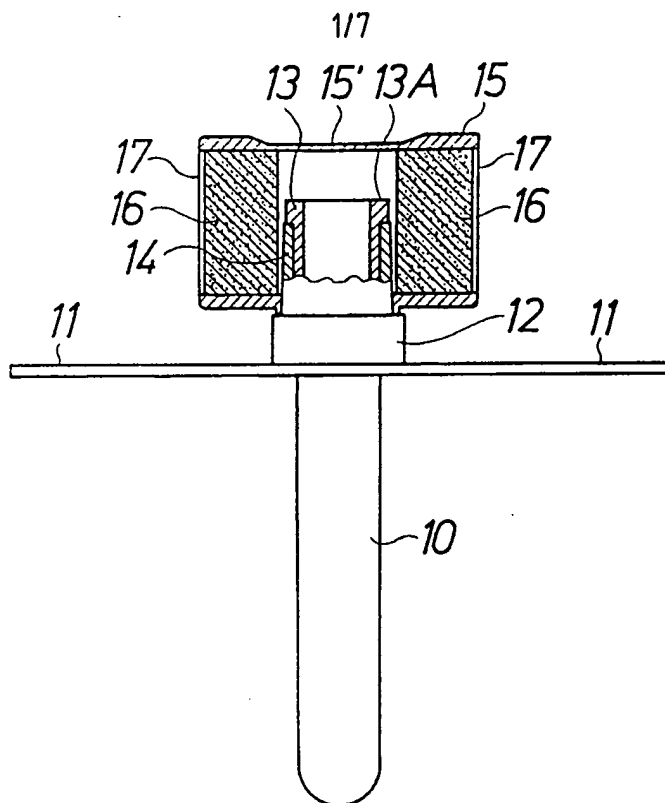


FIG. 1

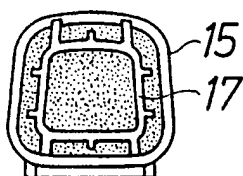


FIG. 2

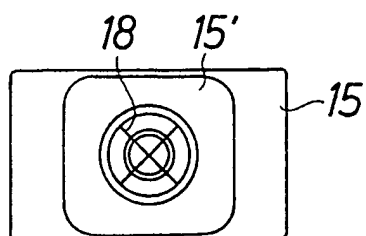


FIG. 3

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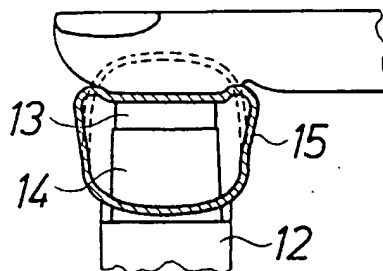


FIG. 4

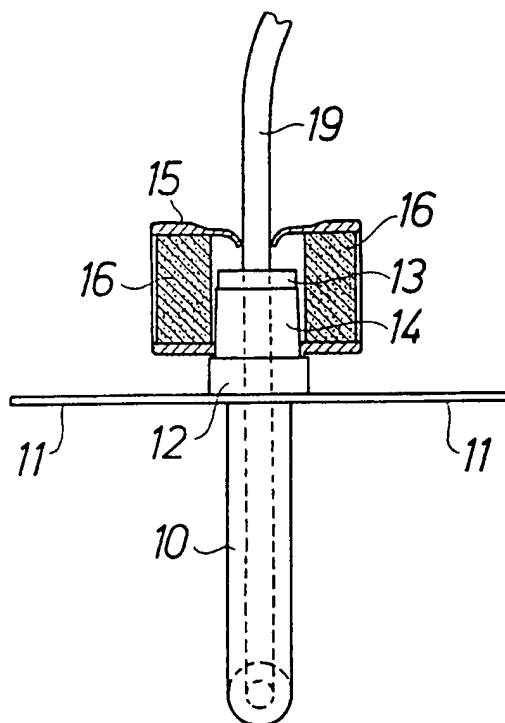


FIG. 5

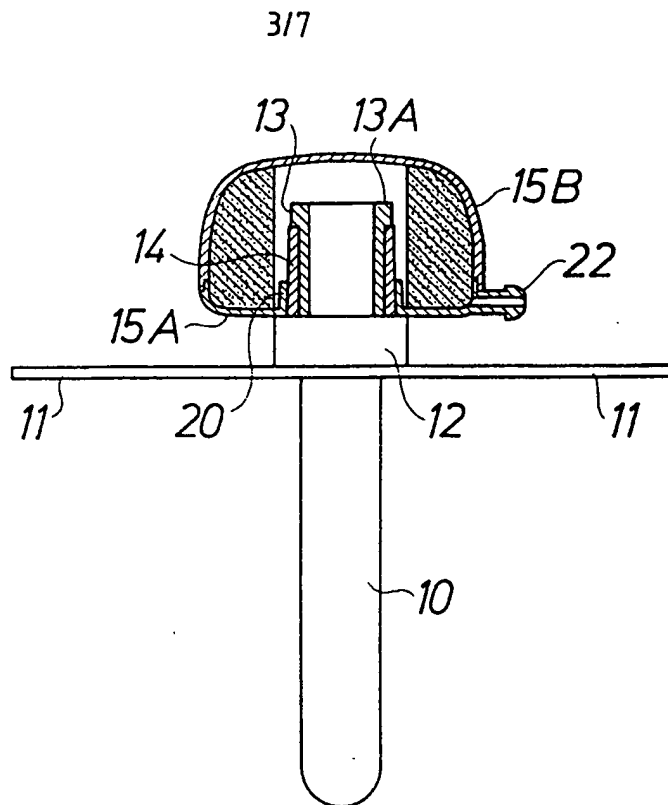


FIG. 6

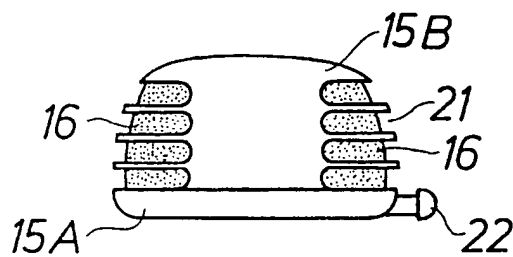


FIG. 7

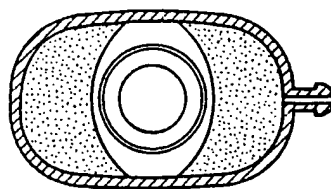


FIG. 8



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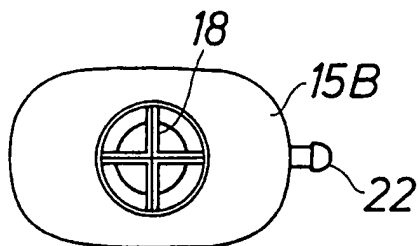


FIG. 9

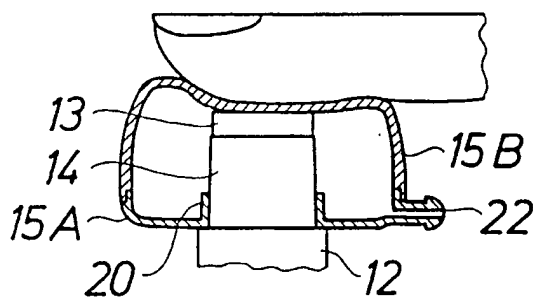


FIG. 10

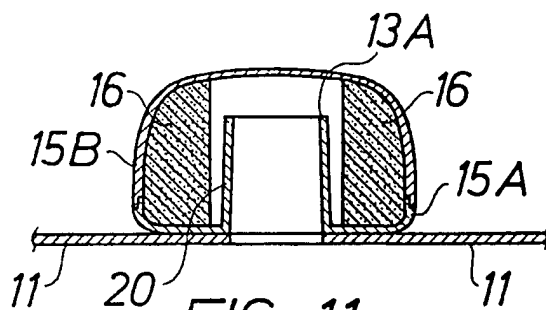


FIG. 11

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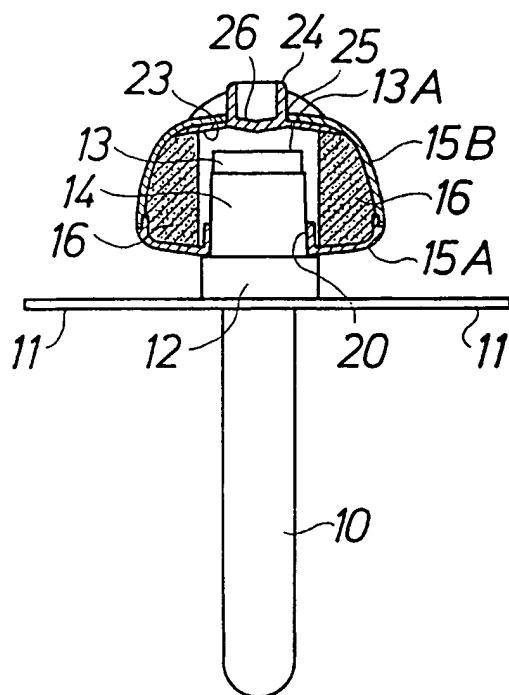


FIG. 12

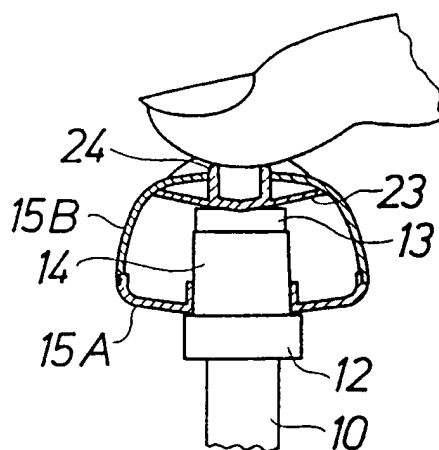


FIG. 13

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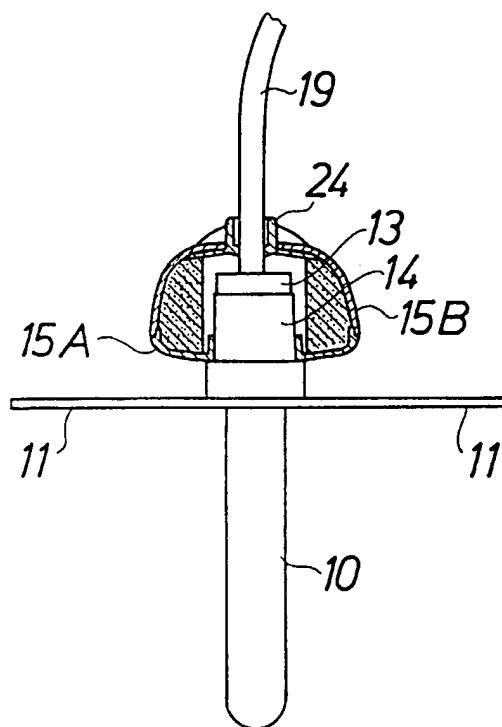


FIG. 14

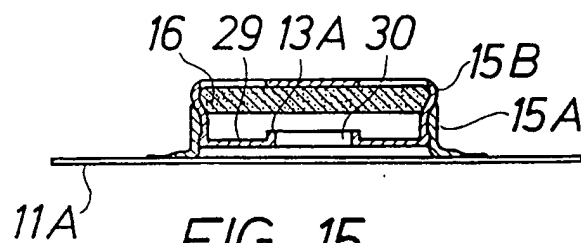


FIG. 15

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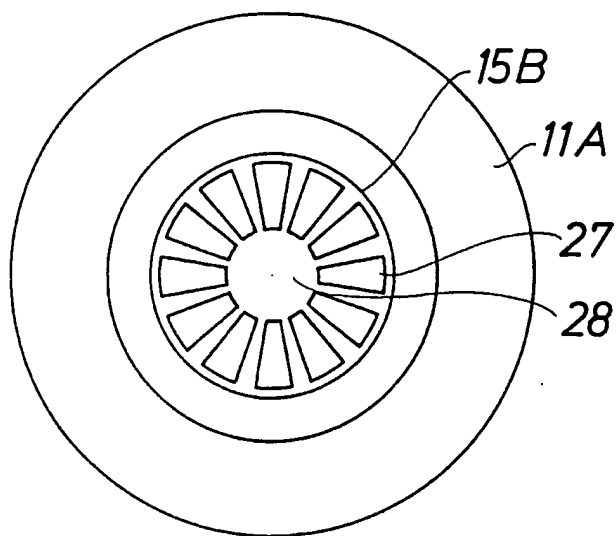


FIG. 16

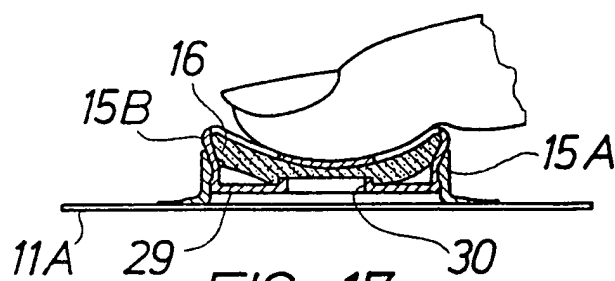


FIG. 17

## INTERNATIONAL SEARCH REPORT

International application No.

PCT/SE 99/00803

## A. CLASSIFICATION OF SUBJECT MATTER

IPC6: A61F 2/20, A61M 16/04

According to International Patent Classification (IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

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## C. DOCUMENTS CONSIDERED TO BE RELEVANT

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A	US 5738095 A (JAN-OVE PERSSON), 14 April 1998 (14.04.98), figure 2, abstract  --	1-12
A	WO 9308860 A1 (BEZICOT, ROBERT), 13 May 1993 (13.05.93), figure 1  -- -----	1-12

☐ Further documents are listed in the continuation of Box C.☒ See patent family annex.

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Date of the actual completion of the international search

14 October 1999

Date of mailing of the international search report

15 -10- 1999

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Leif Brander/ELY

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28/09/99

International application No.  
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